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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/703,399	10/31/2000	Li Zhu	25636-705	2855

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EXAMINER

FRIEND, TOMAS H F

ART UNIT	PAPER NUMBER
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1627

DATE MAILED: 03/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary***file copy*

Application No.

09/703,399

Applicant(s)

ZHU ET AL.

Examiner

Tomas Friend

Art Unit

1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 March 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-9 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **Detailed Action**

### **Status of the Application**

Receipt is acknowledged of a declaration on 09 March 2001 (Paper No. 3).

### **Status of the Claims**

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 63-96 have been renumbered 62-95. Claims 1-95 are pending in the present application and are subject to restriction and election of species requirements.

### **Restriction**

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-49, drawn to a library of expression vectors encoding a library of protein complexes, classified in class 435, digest 23.
  - II. Claims 50-53, drawn to a library of transformed yeast cells, classified in class 435, digest 27.
  - III. Claims 54-61, drawn to a method for generating a library of yeast expression vectors, classified in class 435, digest 47.
  - IV. Claims 62-67, drawn to a method of producing a library of antibodies or antibody fragments, classified in class 435, subclass 7.1.

- V. Claims 68-91, drawn to a method for selecting tester proteins and protein complexes capable of binding to a target peptide or protein, classified in class 435, digest 7.
- VI. Claims 92-95, drawn to a kit comprising first and second populations of haploid yeast cells, classified in class 435, subclass 975.

The inventions are distinct, each from the other because:

- A. Inventions I, II, and VI are different and patentably distinct compositions. Invention I is a library of expression vectors comprising nucleic acid. Invention II is a library of transformed yeast cells comprising yeast cells and recombinant nucleic acid. Invention VI is a kit comprising haploid yeast cells.
- B. Inventions III, IV, and V are different and patentably distinct methods that involve different method steps, produce different results, and/or require different reagents, starting materials, and/or reaction conditions. For example, the method of Invention III produces a library of yeast expression vectors, the method of invention IV produces a library of antibodies or antibody fragments, and the method of Invention V is a method of selecting proteins or protein fragments resulting in the selection of a particular yeast cell or cells.
- C. Inventions III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the library of Invention I can be made by a method not involving yeast cells.
- D. Inventions I and II and Invention IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the Libraries of Inventions I and II can each be used to make libraries of proteins other than antibody or antibody fragments.

E. Inventions I, II and VI and Invention V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the Libraries of Inventions I and II and the kit of Invention VI can be used to produce libraries of recombinant proteins that may be screened by methods other than the method of claim V. For example, each can be used in methods to make libraries of proteins that can be screened immunologically or using enzyme assays.

2. Because these inventions are distinct for the reasons given above and
  - a. have acquired a separate status in the art as shown by their different classification ;
  - b. have different and separately burdensome: manual and/or computer: structure, name and bibliographical searches; and
  - c. have divergent subject matter, restriction for examination purposes as indicated is proper.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under CFR 1.17(h).

#### **Election of Species**

4. This application contains claims directed to the following patentably distinct species of the claimed invention.

A. If applicant elects Invention I, applicant is required under 35 U.S.C. 121 to elect a single disclosed species for both i) and ii) below for prosecution on the merits to which the claims shall

be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 7-15, 33, 34, 48, and 49 are generic.

i) species of vector (e.g. yeast, bacterial, mammalian, viral, retroviral...) AND  
ii) species of protein complex including species of first and second nucleotide sequences (e.g. antibody, heavy domain, light domain or other structurally and/or functionally identifiable combinations such as those listed in claim 16), specifically including **whether or not each of the following are present:**

- a) first and second "zipper" domains,
- b) a bundle domain,
- c) a membrane targeting signal, AND
- d) an ubiquitin sequence.

B. If applicant elects Invention V, applicant is required under 35 U.S.C. 121 to elect a single disclosed species i) - iii) below for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

- i) species of tester protein complexes (e.g. antibodies, antibody fragments, hormone, receptor etc.),
- ii) species of target fusion protein corresponding to the tester protein complexes (e.g. from the list in claim 85), AND
- iii) species of number of target fusion proteins (1 or a plurality).

C. If applicant elects Invention VI, applicant is required under 35 U.S.C. 121 to elect a single disclosed species i) and ii) below for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

- i) species of tester fusion proteins (e.g. antibodies, antibody fragments, hormone, receptor etc.), AND
- ii) species of target fusion protein corresponding to the tester protein complexes.

5. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, **and a listing of all claims readable**

**thereon, including any claims subsequently added.** An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Tomas Friend** at telephone number **(703) 308-4548**. The examiner can normally be reached on Monday, Tuesday, Friday, and Saturday 8:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

*J. Venkat*  
DR. JYOTHSNA VENKAT PH.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

Tomas Friend, Ph.D.

09 March 2002

*TF*